

REMARKS

Claims 1, 12-17, 19-36, 38-46, 48-53, and 75-78 are pending in the present application.

The rejection of Claims 1, 12-17, 19-36, 38-46, 48-53, and 75-78 under 35 U.S.C. §103(a) over Ostroff et al (US 2005/0245480) is respectfully traversed.

In the Office Action mailed October 30, 2008, the Examiner maintained this rejection and provided a “response to arguments” on page 6 of the Office Action. However, the body of the Examiner’s comments relate to Kropf et al, not Ostroff et al. Further, the Examiner’s statement of the traversal argument is completely inaccurate. Indeed, in the response filed June 25, 2008, Applicants reminded the Examiner that Ostroff et al does not qualify as “prior art” as Applicants filed a certified English translation of JP 2001-132513 on August 7, 2006. Thus, this ground of rejection is without merit and should be withdrawn.

Nonetheless, to ensure completeness of the record, Applicants again submit that this ground of rejection over Ostroff et al is traversed on the grounds that this reference is not prior art against the present application for the reasons set forth in the response filed on August 7, 2006 and supported by the certified English translation of JP 2001-132513 filed on the same date.

The present application was filed on October 27, 2003, as a continuation of PCT/JP02/04205, filed on April 26, 2002, which claimed priority to JP 2001-132513 filed on April 27, 2001. Applicants note that the earliest possible effective date as a reference under 35 U.S.C. §102(e) for Ostroff et al (US 2005/0245480) is August 13, 2002. Even giving Ostroff et al (US 2005/0245480) the benefit of this early filing date, this date is more than 3 months after the actual filing date of the present application (i.e., the filing date of

PCT/JP02/04205, which is April 26, 2002) and more than 15-months after the filing date of the priority application (JP 2001-132513) for the present application, which is April 27, 2001. To perfect their claim to foreign priority to JP 2001-132513, Applicants submit a certified English translation of JP 2001-132513 on August 7, 2006.

As recognized by the Examiner on page 3 of the Office Action mailed July 31, 2007 (see paragraph 7), Ostroff et al (US 2005/0245480) is not prior art against the present invention. Applicants again request that the Examiner acknowledge entitlement of the present application to the benefit of an earlier filing date provided by the claim to priority to JP 2001-132513. Further, in recognition of the fact that Ostroff et al (US 2005/0245480) has an earliest effective date under 35 U.S.C. §102(e) after the actual filing date of the present application (i.e., the filing date of PCT/JP02/04205, which is April 26, 2002), Ostroff et al (US 2005/0245480) cannot be prior art. Since Ostroff et al (US 2005/0245480) is not prior art against the present claims this ground of rejection should be withdrawn.

Acknowledgement that this ground of rejection has been withdrawn is requested.

The rejection of Claims 1, 12-17, 19-36, 38-46, 48-53, and 75-78 under 35 U.S.C. §103(a) over Kropf et al is respectfully traversed.

The claimed invention relates to a composition comprising superfine particles of a water extract of a mushroom, wherein the superfine particles have an average particle diameter of 10 µm or less, as determined in the form of a dispersion in water (Claim 1), a method of producing superfine particles comprising superfine pulverizing a β-glucan derived from a water extract of a mushroom (Claim 36), and a process for producing a composition containing superfine particles comprising superfine pulverizing a β-glucan derived from a water extract of a mushroom (Claim 42). Applicants submit that the only β-glucans disclosed

or suggested by Kropf et al are yeast derived glucans. As recognized by the Examiner on page 4, lines 5-6 of the Office Action mailed March 25, 2008, Applicants submit that Kropf et al do not disclose or suggest water extracts of mushroom or β -glucans derived from a mushroom. Therefore, Kropf et al cannot affect the patentability of the claimed invention.

Despite the foregoing, the Examiner alleges on page 4, lines 9-14 of the Office Action mailed March 25, 2008, “where claims are directed to a composition, the manner by which the individual components are obtained is not a patentable distinction if the resulting composition is the same as taught in the prior art... Therefore, any method of obtaining the beta-glucan or source of the beta-glucan would have been obvious to one of ordinary skill in the art at the time of the invention.”

The problems with this allegation by the Examiner are two-fold:

First, Claims 36 and 38-46 do relate to method of making the composition. Accordingly, the method by which the composition is made is a limitation that cannot be disregarded. Accordingly, the fact that Kropf et al do not disclose or suggest water extracts of mushroom or β -glucans derived from a mushroom would mean that Kropf et al cannot affect the patentability of, at least, Claims 36 and 38-46.

Second, the Examiner’s allegation completely fails to attempt and/or provide any evidence to establish that the β -glucans disclosed by Kropf et al, which are yeast derived glucans, are the same as those present in a water extract of mushrooms. Although not stated, it appears that it is the Examiner’s position that the β -glucans disclosed by Kropf et al and obtained from yeast are inherently the same as the β -glucans derived from a water extract of a mushroom as in the claimed invention.

The Examiner is reminded that “[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or

characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). Indeed, “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) In this case, the Examiner has clearly failed to meet this burden as the Examiner does not even attempt to offer any evidence to provide a basis in fact and/or technical reasoning to reasonably support a determination that the allegedly inherent characteristic necessarily flows from the teachings of Kropf et al.

The Examiner is further reminded that the shifting burden requires that the Examiner meet both parts of a two-part test: “Once a reference teaching product appearing to be substantially identical is made the basis of a rejection, **and** the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference.” (MPEP §2112(V)) This burden has not been met in this case as no evidence has been provided to show inherency.

Nonetheless, in the interest of expedient examination, Applicants submit that β -1,3-glucans derived from mushroom, in general, comprises β -1,6-glucans. On the other hand, β -1,3-glucans derived from yeast, does not comprise β -1,6-glucans. Thus, the β -glucans derived from mushroom is distinct from β -glucans derived from yeast as to the presence of β -1,6-glucans.

Support for the foregoing is provided by the following references, which were submitted on June 25, 2008:

1. Documents regarding *Lentinula edodes* (Shiitake) (*Lentinan*)

Sasaki T., Takasuka N., *Carbohydr. Res.*, 47, 99 (1976)

Sasaki T., Takasuka N., Chihara G., Maeda Y. Y., Gann, 67, 191 (1976)

Saito H., Ohki T., Sasaki T., Biochem. 16, 908 (1977)

2. Document regarding Schizophyllum commune (Sizofiran)

Tabata K., Ito W., Kojima T. et al Carbohydr. Res., 89, 121 (1981)

3. Document regarding Sclerotium (Scleroglucan)

Falch B H, Espevik T, Ryan L et al. Carbohydr. Res., 329, 587 (2000)

Applicants wish to further note that, at least, Claims 14-17, 19, 21-24, 35, 38, 39, 43, and 44 require the presence of a dispersant. Kropf et al make no mention of the presence of the dispersant when the average particle diameter is of 10 μm or less. An important aspect of this embodiment of the present invention is that the β -glucan derived from the water extract of a mushroom is mixed with a dispersant to prepare the superfine particles having an average particle diameter of 10 μm or less (see, for example, Claim 14, and page 28, line 16 to 21 of the present specification); and the β -glucan obtained thereby are significantly improved in incorporation through mucosa so that immune functions can be activated or regulated. These technical features are not obvious over Kropf et al since the particle size of β -glucan disclosed in Kropf et al is measured without a dispersant.

In the Office Action mailed October 30, 2008, the Examiner maintained the rejection of the claims as being obvious in view of Kropf et al. The Examiner contends that, although Applicants have provided evidence that mushrooms comprise β -1,6-glucans, they have failed to provide any evidence that yeast disclosed by Kropf et al are devoid of β -1,6-glucans. Applicants direct the Examiner's attention to the previously cited references, which show that the only β -glucans derived from yeast are β -1,3-glucans or β -glucans having both 1 \rightarrow 3-linked and 1 \rightarrow 6-linked glucose residues, which are distinct from the β -1,6-glucans derived from mushrooms.

Further, Applicants **submit herewith** the following references:

- a. "Zymosan", Wikipedia entry retrieved January 26, 2009 at
<http://en.wikipedia.org/wiki/Zymosan>;
- b. "β-glucan", Wikipedia entry retrieved January 27, 2009 at
<http://en.wikipedia.org/wiki/Beta-glucan>;
- c. Tada R, et al., Glycoconj. J. 25:851-861, 2008;
- d. Oshiman K, et al., Planta Med. 8:610-614, 2002.

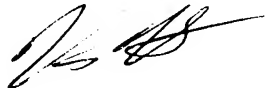
References (a) - (c) show that β-glucans derived from yeast are mostly β-glucans having β-1,3-linked main chains (partly, having β-1,6-linked branched chains (residues)). Reference (d) shows that β-glucans derived from mushroom has β-1,6-linked main chains, not β-1,6-linked as a residue. Accordingly, as further supported by these new references, Applicants submit that the claimed invention is distinct and non-obvious in view of the disclosure of Kropf et al.

In view of the foregoing, withdrawal of this ground of rejection is requested.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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